

Docket No. 366325-120  
US App. No. 09/340,338

IN THE CLAIMS

1-42. (Canceled)

2 43. (Currently amended) The delivery device of claim [42] <sup>1</sup>~~42~~, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.

8 44. (Currently amended) [The delivery device of claim 43,] A delivery device for treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the device does not comprise a backing layer, wherein the device does not comprise a release liner, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer, and wherein the disk comprises 70 to 95 wt% filmogenic polymer.

9 45. (Previously presented) The delivery device of claim <sup>8</sup>~~44~~, wherein the filmogenic polymer is polyvinyl pyrrolidone.

10 46. (Previously presented) The delivery device of claim <sup>8</sup>~~44~~, wherein the filmogenic polymer is gliadin.

11 47. (Currently amended) The delivery device of claim [42] <sup>8</sup>~~44~~, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an  $\alpha$ -blocker, and a calcium channel blocker.

12 48. (Currently amended) The delivery device of claim [42] <sup>8</sup>~~44~~, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a

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yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxisylyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

1 49. (Currently amended) [The delivery device of claim 42,] A delivery device for treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the device does not comprise a backing layer, wherein the device does not comprise a release liner, and wherein the therapeutic agent is misoprostol.

13 50. (Currently amended) The delivery device of claim [42] <sup>8</sup>/~~44~~, wherein the therapeutic agent is a prostaglandin.

14 51. (Previously presented) The delivery device of claim <sup>13</sup>/~~50~~, wherein the therapeutic agent is prostaglandin E1.

3 52. (Currently amended) The delivery device of claim [42] <sup>1</sup>/~~48~~, wherein the disk further comprises a plasticizer in an amount of less than 30 wt%.

4 53. (Previously presented) The delivery device of claim <sup>3</sup>/~~52~~, wherein the plasticizer is a polyethylene glycol (PEG).

5 54. (Previously presented) The delivery device of claim <sup>4</sup>/~~53~~, wherein the polyethylene glycol is PEG 400.

6 55. (Currently amended) The delivery device of claim [42] <sup>1</sup>/~~49~~, wherein the delivery device is a transdermal device.

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7 56. (Currently amended) The delivery device of claim [42] <sup>1</sup>~~42~~, wherein the delivery device is a transmucosal device.

15 57. (Previously presented) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the disk comprises 70 to 95 wt% filmogenic polymer.

17 58. (Previously presented) The delivery device of claim <sup>15</sup>~~57~~, wherein the filmogenic polymer is polyvinyl pyrrolidone.

18 59. (Previously presented) The delivery device of claim <sup>15</sup>~~57~~, wherein the therapeutic agent is misoprostol.

19 60. (Previously presented) The delivery device of claim <sup>15</sup>~~57~~, wherein the therapeutic agent is a prostaglandin.

20 61. (Previously presented) The delivery device of claim <sup>19</sup>~~60~~, wherein the prostaglandin is prostaglandin E1.

21 62. (Previously presented) The delivery device of claim <sup>15</sup>~~57~~, wherein the mixture of materials further comprises a plasticizer in an amount of less than 30 wt%.

22 63. (Previously presented) The delivery device of claim <sup>21</sup>~~62~~, wherein the plasticizer is a polyethylene glycol (PEG).

23 64. (Previously presented) The delivery device of claim <sup>22</sup>~~63~~, wherein the polyethylene glycol is PEG 400.

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65. (Previously presented) The delivery device of claim <sup>15</sup>~~57~~, wherein the delivery device is a transdermal device.

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66. (Previously presented) The delivery device of claim <sup>15</sup>~~57~~, wherein the delivery device is a transmucosal device.

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67. (Previously presented) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone and an effective dose of a therapeutic agent suitable for treating erectile dysfunction.

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68. (Previously presented) The delivery device of claim <sup>28</sup>~~67~~, wherein the therapeutic agent is misoprostol.

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69. (Previously presented) The delivery device of claim <sup>28</sup>~~67~~, wherein the therapeutic agent is a prostaglandin.

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70. (Previously presented) The delivery device of claim <sup>32</sup>~~69~~, wherein the prostaglandin is prostaglandin E1.

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71. (Previously presented) The delivery device of claim <sup>28</sup>~~67~~, wherein the mixture of materials further comprises a plasticizer.

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72. (Previously presented) The delivery device of claim <sup>34</sup>~~71~~, wherein the plasticizer is a polyethylene glycol (PEG).

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73. (Previously presented) The delivery device of claim <sup>35</sup>~~72~~, wherein the polyethylene glycol is PEG 400.

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37 74. (Previously presented) The delivery device of claim <sup>26</sup>~~67~~, wherein the delivery device is a transdermal device.

38 75. (Previously presented) The delivery device of claim <sup>26</sup>~~67~~, wherein the delivery device is a transmucosal device.

39 76. (Previously presented) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone, an effective dose of a therapeutic agent suitable for treating erectile dysfunction and a plasticizer, wherein the device does not comprise a backing layer and wherein the device does not comprise a release liner.

40 77. (Previously presented) The delivery device of claim <sup>39</sup>~~76~~, wherein the therapeutic agent is misoprostol and the plasticizer is PEG 400.

41 78. (Previously presented) The delivery device of claim <sup>39</sup>~~76~~, wherein the therapeutic agent is a prostaglandin.

42 79. (Previously presented) The delivery device of claim <sup>41</sup>~~78~~, wherein the prostaglandin is prostaglandin E1.

45 80. (Previously presented) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk; wherein the disk is made of a mixture of materials comprising 70 to 95 wt% filmogenic polymer, an effective dose of a therapeutic agent suitable for treating erectile dysfunction, and at least one additive selected from the group consisting of a stabilizer, a solubilizer, and enhancer and a plasticizer.

46 81. (Previously presented) The delivery device of claim <sup>45</sup>~~80~~, wherein the at least one additive comprises an enhancer selected from the group consisting of a

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glycolipid, a non-esterified fatty acid, an aliphatic alcohol, a fatty acid ester of an aliphatic alcohol, a cyclohexanol, a fatty acid ester of glyccrol, a glycol, an aliphatic alcohol ether of a glycol, and a surfactant.

47 82. (Previously presented) The delivery device of claim <sup>45</sup>80, wherein the therapeutic agent is a prostaglandin.

48 83. (Previously presented) The delivery device of claim <sup>47</sup>82, wherein the prostaglandin is prostaglandin E1.

49 84. (Previously presented) The delivery device of claim <sup>47</sup>82, wherein the at least one additive comprises a plasticizer.

50 85. (Previously presented) The delivery device of claim <sup>49</sup>84, wherein the plasticizer is a polyethylene glycol.

54 86. (Previously presented) A method of treating erectile dysfunction, comprising:

- selecting a device comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the disk comprises 70 to 95 wt% filmogenic polymer, wherein the device does not comprise a backing layer and wherein the device does not comprise a release liner;

- wetting a penile surface; and

- placing the device in contact with the wetted surface, thereby wetting the disk and delivering the at least one therapeutic agent to the penile surface in a time period that is desirable to obtain a positive response.

55 87. (Previously presented) The method according to claim <sup>54</sup>86, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle

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relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an  $\alpha$ -blocker, and a calcium channel blocker.

56 88. (Previously presented) The method according to claim ~~86~~<sup>54</sup>, wherein the therapeutic agent is selected from the group consisting of a prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

57 89. (Previously presented) The method according to claim ~~86~~<sup>54</sup>, wherein the therapeutic agent is present in a range of 0.1-15 wt%.

58 90. (Previously presented) The method according to claim ~~88~~<sup>56</sup>, wherein the therapeutic agent is misoprostol.

59 91. (Previously presented) The method according to claim ~~86~~<sup>54</sup>, wherein the plasticizer is present in an amount that is less than 30 wt%.

60 92. (Previously presented) The method according to claim ~~91~~<sup>59</sup>, wherein the plasticizer is a polyethylene glycol (PEG).

61 93. (Previously presented) The method according to claim ~~92~~<sup>60</sup>, wherein the polyethylene glycol is PEG 400.

62 94. (Previously presented) The method according to claim ~~86~~<sup>54</sup>, wherein the filmogenic polymer is a synthetic polymer.

63 95. (Previously presented) The method according to claim ~~94~~<sup>62</sup>, wherein the synthetic polymer is polyvinyl pyrrolidone.

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65 96. (Currently amended) The method according to claim [86] <sup>64</sup>~~112~~, wherein the filmogenic polymer is a plant protein.

66 97. (Previously presented) The method according to claim <sup>65</sup>~~96~~, wherein the plant protein is a prolamine.

67 98. (Previously presented) The method according to claim <sup>66</sup>~~97~~, wherein the prolamine is a gliadin.

68 99. (Previously presented) The method according to claim <sup>54</sup>~~86~~, wherein the time period is 5-100 minutes.

69 100. (Previously presented) The method according to claim <sup>68</sup>~~99~~, wherein the time period is 30-60 minutes.

70 101. (Previously presented) The method according to claim <sup>54</sup>~~86~~, wherein the penile surface is selected from the group consisting of (a) the shaft, (b) the glans and (c) both the shaft and the glans.

71 102. (Previously presented) A method of treating erectile dysfunction, comprising:

selecting a device comprising a disk, wherein the disk is made of a mixture of materials, wherein the disk is made of a mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone, polyethylene glycol and an effective dose of misoprostol suitable for treating erectile dysfunction;

wetting a penile surface; and

placing the device in contact with the wetted surface, thereby wetting the disk and delivering the at least one therapeutic agent to the penile surface in a time period that is desirable to obtain a positive response.



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103. (Previously presented) The method according to claim <sup>71</sup>~~102~~, wherein the penile surface is selected from the group consisting of (a) the shaft, (b) the glans and (c) both the shaft and the glans.

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104. (New) The delivery device of claim <sup>15</sup>~~57~~, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an  $\alpha$ -blocker, and a calcium channel blocker.

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105. (New) The delivery device of claim <sup>15</sup>~~57~~, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

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106. (New) The delivery device of claim <sup>28</sup>~~57~~, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an  $\alpha$ -blocker, and a calcium channel blocker.

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107. (New) The delivery device of claim <sup>28</sup>~~57~~, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

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108. (New) The delivery device of claim <sup>39</sup>~~76~~, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an  $\alpha$ -blocker, and a calcium channel blocker.

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43 109. (New) The delivery device of claim <sup>39</sup>~~76~~, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

53 110. (New) The delivery device of claim <sup>45</sup>~~80~~, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an  $\alpha$ -blocker, and a calcium channel blocker.

62 111. (New) The delivery device of claim <sup>45</sup>~~80~~, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

64 112. (New) The delivery device of claim <sup>54</sup>~~86~~, wherein the filmogenic polymer is a naturally occurring polymer.

16 113. (New) The delivery device of claim <sup>15</sup>~~51~~, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.

51 114. (New) The delivery device of claim <sup>45</sup>~~80~~, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.